

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA

v.

MURTY VEPURI  
ASHVIN PANCHAL  
KVK-TECH, INC.

Case No. 21-132-HB

The Hon. Harvey Bartle III

**O R D E R**

AND NOW, this \_\_\_\_\_ day of \_\_\_\_\_, 2021, upon consideration of Defendant Murty Vepuri's Motion to Dismiss the Superseding Indictment As Time Barred under Federal Rule of Criminal Procedure 12, it is hereby ORDERED that the motion is GRANTED. The Superseding Indictment is dismissed in its entirety.

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HON. HARVEY BARTLE III  
JUDGE, U.S. DISTRICT COURT

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**ORAL ARGUMENT REQUESTED**

**DEFENDANT MURTY VEPURI'S MOTION TO DISMISS  
THE SUPERSEDING INDICTMENT AS TIME BARRED  
UNDER FEDERAL RULE OF CRIMINAL PROCEDURE 12**

Defendant Murty Vepuri, by and through his undersigned counsel, hereby moves to dismiss the Superseding Indictment as time barred under Federal Rule of Criminal Procedure 12. In support of this Motion, Defendant Vepuri relies upon the attached memorandum of law, which is incorporated herein.

WHEREFORE, Defendant Vepuri respectfully requests that this Court enter the attached Order dismissing the Superseding Indictment in its entirety.

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Dated: December 1, 2021

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**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT MURTY VEPURI'S  
MOTION TO DISMISS THE SUPERSEDING INDICTMENT  
AS TIME BARRED UNDER FEDERAL RULE OF CRIMINAL PROCEDURE 12**

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## **INTRODUCTION**

Although artfully drafted to suggest multiple distinct objectives, in fact the overriding objective of the conspiracy alleged in Count 1 was to impede, impair, and defeat the lawful functioning of the U.S. Food and Drug Administration (“FDA”) by introducing unapproved new drugs into interstate commerce. That alleged objective was accomplished no later than December 2013—*i.e.*, about seven-and-a-half years prior to the Superseding Indictment’s return in June 2021. It is well established, black letter law, that subsequent alleged efforts at concealment could not and did not extend the conspiracy, once the overriding object of the conspiracy was achieved. Because the government’s efforts to sprinkle allegations of concealment do not extend the already accomplished conspiracy, the concealment allegations do not cure the Superseding Indictment’s statute of limitations flaw. The untimely Superseding Indictment must be dismissed.

## **BACKGROUND**

### ***The Overriding Object Of The Alleged Conspiracy Was Achieved By December 2013***

On June 10, 2021, the Government filed the Superseding Indictment charging Murty Vepuri, Ashvin Panchal, and KVK with one count of conspiracy to defraud and commit an offense against the United States, by: (1) conspiring to impede, impair, and defeat the lawful function of the FDA, in violation of 18 U.S.C. § 371; (2) conspiring to introduce unapproved new drugs into interstate commerce with intent to defraud and mislead, in violation of 18 U.S.C. § 371 and contrary to 21 U.S.C. § 331(d) and 335(a); and (3) conspiring to make false and misleading statements to the FDA, in violation of 18 U.S.C. § 371, and contrary to 18 U.S.C. § 1001. *See* Superseding Indictment at 6 ¶ 16.

Notably, the period of the alleged conspiracy is from “in or about October 2010 through at least in or about March 2015,” with the conspiracy allegedly bookended by overt acts or omissions occurring on October 29, 2010 and March 2, 2015. *See id.* at 6 ¶ 16; 7 ¶ 1; 14 ¶ 19.

Despite the lengthy conspiracy period charged in the Superseding Indictment, the alleged overriding purpose of defendants—*i.e.*, to distribute unapproved product—was accomplished well before the date the government alleges the conspiracy ended. Specifically, the Superseding Indictment alleges that “[d]uring the period from in or about April 2011 through at least in or about December 2013, defendant KVK-TECH delivered to its customers approximately 62 batches of Hydroxyzine tablets made from unapproved HCL API, containing at least approximately 368,311 bottles, for distribution to patients throughout the United States.” *See id.* at 10 ¶ 9. In other words, the conspiracy’s central alleged objective was achieved by **December 2013**.

Thus, the essential gravamen of the government’s conspiracy charge is that, nearly a decade ago, KVK failed to obtain the FDA’s advance approval (by failing to file certain paperwork with the FDA) when, even earlier still, KVK’s Active Pharmaceutical Ingredient (API) manufacturer subcontracted certain manufacturing processes to another facility. Significantly, that facility change resulted in no patient harm or product impact, as testing by KVK, the API manufacturer, and the FDA itself demonstrated that the product from the two facilities was equivalent (and therefore interchangeable); the supplier in fact had informed the FDA of the change in manufacturing location; and the FDA ultimately approved the change when KVK did provide the relevant testing data. (Importantly, FDA also never took adverse administrative action against Mr. Vepuri, Mr. Panchal, or KVK in connection with the alleged reporting lapse on which this criminal indictment is based.) Thus, having initially determined it did not need to file certain paperwork that FDA later requested, KVK nonetheless subsequently did file the paperwork and FDA approved the product.

***The Government’s Allegation Of Acts (And Omissions) After December 2013***

The government alleges that shipment of unapproved product occurred between April 2011 and December 2013. *See* Superseding Indictment at 10 ¶ 9. Apparently realizing its failure to

charge this conduct within the required five-year statute of limitations (*i.e.*, before December 2018), the government adds various alleged acts of concealment (and omissions) in an effort to artificially extend the statute of limitations. Thus, for example, the Superseding Indictment includes the following alleged “overt acts” after December 2013:

- Allegedly false statements made by Mr. Vepuri<sup>1</sup> and co-defendant Ashvin Panchal at a meeting with the FDA on **June 27, 2014**, *see* Superseding Indictment at 13 ¶¶ 16-17;
- Allegedly false statements made by Mr. Panchal in a Manufacturing Deviations and Investigations (MDI) report purportedly provided to the FDA on **December 11, 2014**,<sup>2</sup> *see* Superseding Indictment at 13-14 ¶ 18; and
- An alleged failure to notify FDA about allegedly false statements in the final Establishment Inspection Report (EIR) FDA released on **March 2, 2015**, *see* Superseding Indictment at 14 ¶ 19.

In sum, these post-December 2013 alleged acts involve: (1) the government’s mistaken belief in Mr. Vepuri’s presence at a meeting that he actually did not attend; (2) allegedly false statements attributed to someone other than Mr. Vepuri; and (3) conduct not by Mr. Vepuri or another other alleged conspirator, but rather conduct by the government (the release of the EIR) with statements the alleged conspirators allegedly failed to correct.

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<sup>1</sup> By email dated October 5, 2021, undersigned counsel advised the government’s counsel, under Federal Rule of Criminal Procedure 12.1 (regarding alibi defenses) that the allegation regarding Mr. Vepuri is factually incorrect, as Mr. Vepuri did not in fact participate in the FDA meeting. Thus, the grand jurors’ adoption of this allegation was based upon a false premise.

<sup>2</sup> As noted in the Motion to Dismiss of Mr. Vepuri’s co-defendant, Mr. Panchal, December 11, 2014 was merely the date the FDA inspection concluded. *See* Motion to Dismiss of Ashvin Panchal at 19. The MDI Report actually was provided to the FDA for the first time on January 15, 2014, and again on November 20, 2014.

***The Government's Reliance Upon Six Months Of MLAT Tolling  
Between December 23, 2016 And March 22, 2018***

In correspondence with prior counsel for Mr. Vepuri, the government has suggested that it is entitled to at least six months of tolling of the statute of limitations due to its pursuit of foreign evidence under the process permitted via Mutual Legal Assistance Treaty (MLAT). In fact, the government is entitled to a maximum of six months of tolling.<sup>3</sup> Specifically, based upon the discovery the government has provided to date, it appears that:

- The government made an “official request” for foreign evidence under the MLAT procedure on December 23, 2016. *See* Order of Hon. Cynthia M. Rufe (Feb. 28, 2017), attached as Exhibit A ¶ 5.
- The government submitted an *ex parte* Application for tolling of the statute of limitations based upon an Affidavit of Special Agent Kathleen Scioli that was sworn out on February 27, 2017. *Id.* ¶ 3.
- The Honorable Judge Cynthia M. Rufe granted the government’s request for tolling on February 28, 2017, concluding that “the running of the statute of limitations for the offenses set forth in the government’s *ex parte* Application” would be suspended “for the period indicated in 18 U.S.C. § 3292(c).” *Id.* at 2.
- The Central Authority of Belgium responded to the “official request” of the United States on January 8, 2018 and March 22, 2018. *See* Exhibits B and C.

Thus, based upon Judge Rufe’s tolling Order issued under 18 U.S.C. § 3292(a), the government is entitled to a maximum of six months of tolling during the period from the date of the “official request” (*i.e.*, December 23, 2016) through the date of the foreign authority’s “final action” (*i.e.*, March 22, 2018). *See* 18 U.S.C. § 3292(b)-(c).

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<sup>3</sup> The six-month limit applies under § 3292(c)(2) because, absent tolling, the statute of limitations would have run after the foreign authority’s final action on March 22, 2018.

***Additional Agreed-Upon Tolling Between Mr. Vepuri And The Government  
From September 9, 2019 To May 17, 2019***

To facilitate plea discussions with the government, Mr. Vepuri agreed to enter into a series of tolling agreements with the government, beginning September 9, 2019.<sup>4</sup> *See Exhibit D.* Tolling under those agreements ended by May 17, 2021. Thus, given the tolling period under these agreements from September 9, 2019 through May 17, 2021, and the return of the Superseding Indictment on June 10, 2021, 24 days are added back to the clock to account for the intervening time period between the end of the tolling agreements and the filing of the Superseding Indictment.

\* \* \*

In sum, the upshot of all applicable tolling periods means the following, given the five-year statute of limitations period applicable to a conspiracy charge under 18 U.S.C. § 3282(a):

- The first agreed-upon tolling as of September 9, 2019, minus five years takes the last possible overt act in furtherance of the conspiracy back to September 9, 2014.
- The addition of six months of MLAT tolling takes the last possible overt act in furtherance of the conspiracy back to March 9, 2014.
- The lack of tolling on 24 days (due to the intervening period between the expiration of the tolling agreements and the filing of the Superseding Indictment) means 24 days are added back to the clock, so that the last possible overt act in furtherance of the conspiracy cannot be earlier than April 2, 2014.

Accordingly, the tolling carveouts applicable to Mr. Vepuri mean that Mr. Vepuri cannot be charged with conspiracy arising from an overt act by *himself or any other alleged coconspirator* occurring before April 2, 2014.

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<sup>4</sup> The tolling agreements appeared to bear fruit, as they resulted in a plea agreement to a misdemeanor charge of introducing unapproved new drugs into interstate commerce, which the government filed on April 5, 2021. *See Dkt. No. 1.* Ultimately, Mr. Vepuri withdrew from the agreement in the weeks prior to the passing of his wife of many years.

## **ARGUMENT**

### **I. The Superseding Indictment Should Be Dismissed As Time Barred**

#### **A. Applicable Law**

A five-year statute of limitations applies to a violation of Title 18, United States Code, Section 371. *See* 18 U.S.C. § 3282(a) (“Except as otherwise expressly provided by law, no person shall be prosecuted, tried, or punished for any offense, not capital, unless the indictment is found or the information is instituted within five years next after such offense shall have been committed.”). “For a conspiracy indictment to fall within the statute of limitations, it is incumbent on the Government to prove that . . . at least one overt act in furtherance of the conspiracy was performed within five years of the date the Indictment was returned.” *United States v. Bornman*, 559 F.3d 150, 153 (3d Cir. 2009), *as amended* (Apr. 24, 2009), *as amended* (May 5, 2009) (internal citation omitted).

To determine whether an act furthers a conspiracy, and therefore is within the statute of limitations, “the crucial question . . . is the scope of the conspiratorial agreement.” *Grunewald v. United States*, 353 U.S. 391, 397 (1957). After the conspiratorial objective is accomplished, subsequent acts to cover up or conceal the already completed conspiracy cannot, by definition, be overt acts in furtherance of it. *See id.* at 401-02 (“[A]fter the central criminal purposes of a conspiracy have been attained, a subsidiary conspiracy to conceal may not be implied from circumstantial evidence showing merely that the conspiracy was kept a secret and that the conspirators took care to cover up their crime in order to escape detection and punishment.”); *see also United States v. Fattah*, 223 F. Supp. 3d 336, 353 (E.D. Pa. 2016) (Bartle, J.) (“Concealment activities after the purpose of the conspiracy has been attained ‘for the purpose only of covering up after the crime’ do not extend the time to file an indictment.”), *aff’d in part, rev’d in part*, 902 F.3d 197 (3d Cir. 2018) and *aff’d in part, rev’d in part*, 914 F.3d 112 (3d Cir. 2019).

This of course makes sense. Otherwise, acts of concealment after a conspiracy's objective is achieved "would result in a great widening of the scope of conspiracy prosecutions," and "extend the life of a conspiracy indefinitely." *Grunewald*, 353 U.S. at 402. In addition to "wip[ing] out the statute of limitations in conspiracy cases," this would also have the harmful evidentiary impact of "extend[ing] indefinitely the time within which hearsay declarations will bind co-conspirators."

*Id.*

In sum, *Grunewald*'s focus upon "the scope of the conspiratorial agreement," and its "central criminal purpose" is "crucial" in order to know whether or not subsequent alleged acts of concealment further the conspiracy's central purpose (and therefore extend the life of the conspiracy).

**B. Alleged Acts And Omissions After The Conspiracy Achieved Its Alleged Objective In December 2013 Do Not Extend The Statute Of Limitations**

In the language of *Grunewald*, "the central criminal purpose" of the conspiracy alleged in Count 1—its *raison d'être*—was purportedly to distribute an unapproved new drug. *Grunewald*, 353 U.S. at 405. That core objective was achieved by December 2013. And, notably, the Superseding Indictment's description of the *distribution object* of the conspiracy (separate and distinct from the § 1001 violation object of the conspiracy) does not include—as *Grunewald* requires—any allegation of "an express original agreement among the conspirators to continue to act in concert in order to cover up . . . traces of the crime after its commission." *Grunewald*, 353 U.S. at 404. In other words, there is no alleged agreement *to unlawfully distribute and to conceal the unlawful distribution*.

Accordingly, subsequent alleged overt acts (of concealment, or otherwise) did not and could not further, in any way, the already accomplished distribution objective. As noted below, the alleged overt acts were not acts of concealment at all. Even if they were, they were not in

furtherance of the distribution object of the conspiracy. Thus, *Grunewald* and its progeny require this Court to make the “vital distinction . . . between acts of concealment done in furtherance of the main criminal objectives of the conspiracy, and acts of concealment done after these central objectives have been attained, for the purpose only of covering up after the crime.” *Id.* at 405.

**1. The Alleged Acts on June 27, 2014 and December 11, 2014 Were not Acts of Concealment, and Did not Further the Conspiracy Even if They Were**

Paragraph 16 of the Superseding Indictment alleges that Mr. Vepuri and Mr. Panchal, at a meeting with the FDA on June 27, 2014, “continued to promote the false narrative that a mistake by a former employee had caused the company to inadvertently manufacture and distribute Hydroxyzine containing the HCL AP manufactured by DRL in Mexico.” Superseding Indictment at 13 ¶ 16. Putting aside, for now, the issue of fact that such statements, even if made, were neither false nor material (and also putting aside the government’s mistaken conclusion that Mr. Vepuri participated in the meeting, *see* supra note 1), those statements did nothing to promote the conspiracy to distribute unapproved new drugs. This is because, at most—even viewing the evidence in the light most favorable to the government—the statements could only have concealed an already accomplished conspiratorial objective to distribute. Moreover, the FDA discovered the sale of the allegedly unapproved drugs in November 2013, *see* Superseding Indictment at 11 ¶ 14, and KVK subsequently issued a recall for all of the allegedly unapproved product. Thus, nothing Mr. Vepuri or Mr. Panchal said (or failed to say) on June 27, 2014 or December 11, 2014 could have furthered anything. No unapproved drug product was being distributed at that time.

The same is true of Paragraph 17 of the Superseding Indictment, which alleges that Mr. Vepuri, at the same meeting with the FDA on June 27, 2014, “identified himself to the FDA as an advisor to defendant KVK-TECH in order to conceal that he was the *de facto owner* of the company” as well as directed its daily operations and made important business decisions for KVK.

Superseding Indictment at 13 ¶ 17. Putting aside, once more, the fact that such statements could not possibly have been made by Mr. Vepuri, given his provable absence from the meeting, and that those statements (even if they had been made) were neither false nor material, they could not have promoted the conspiracy to distribute unapproved product.

Paragraph 18 of the Superseding Indictment merely repeats the same theme. It alleges that Mr. Panchal submitted the MDI Report on December 11, 2014, knowing that it “contained false and misleading information, including that it was ‘not clear why the manufacturer UCB Pharma S.A. shipped API manufactured in Mexico.’” Superseding Indictment at 13-14 ¶ 18. Putting aside the fact that such statements were neither false nor material, they could not have promoted the conspiracy to distribute unapproved product, as that was accomplished no later than December 2013. At most, they could only have concealed the already accomplished conspiratorial objective.

Each of the above statements, even assuming them to have been concealing, exemplify the *Grunewald* problem by alleging overt acts that *followed*, and therefore were unnecessary to accomplishing, the alleged conspiracy’s distribution objective. In this sense the alleged conduct attributed to Mr. Vepuri is akin to the conduct of the husband in *Roshko*, who was charged with conspiring to enter into a sham marriage for the purpose of changing his immigration status, and whose subsequent divorce and remarriage the Second Circuit held did not extend the conspiracy. The husband’s “acquisition of a green card was the object of the conspiracy alleged in this indictment. The subsequent alleged overt acts—his divorce and his marriage to Irene—were superfluous to the success of that object.” *United States v. Roshko*, 969 F.2d 1, 8 (2d Cir. 1992).

**2. The Alleged Omission on March 2, 2015 was not an Act of Concealment, and Could not Further the Conspiracy Even if it was**

Paragraph 19 alleges conduct, not by a conspirator at all, but by the FDA itself—namely, the FDA’s release of an EIR on March 2, 2015—and the alleged conspirators’ failure to correct

statements in the EIR. Superseding Indictment at 14 ¶ 19. Specifically, the allegation is that the conspirators “failed to notify the FDA of the falsehoods to avoid enforcement action or being required to perform needed corrective actions.” *Id.* The Superseding Indictment alleges no duty requiring defendants to correct the EIR, nor are we aware of one.

The statute of limitations problem is particularly acute when it comes to overt “acts” that are in fact not acts at all, but rather failures to act (*i.e.*, omissions). Under those circumstances, the failure to act is even more clearly not in furtherance of the conspiracy, and therefore does not extend the limitations period. For example, the Fifth Circuit has held that a § 371 conspiracy to make false statements to the government, contrary to § 1001, was complete when the false statement was made, and the failure to correct the falsity was not a continuing offense that could extend the limitations. *See United States v. Davis*, 533 F.2d 921 (5th Cir. 1976).

So too, receipt of a loan may accomplish an unlawful objective, but the subsequent failure to repay it (*i.e.*, to remedy the wrong)—despite the benefit the borrower enjoys throughout the period of nonpayment—does not extend the conspiracy. *See, e.g., United States v. Hare*, 618 F.2d 1085 (4th Cir. 1980); *Bornman*, 559 F.3d at 153 (noting refusal to return improper payment did not further conspiracy to obtain payment, or extend the limitations on the conspiracy to obtain the payment). Otherwise, the government would enjoy a practically limitless period in which to charge, which “would be contrary to the Supreme Court’s admonition in *Toussie v. United States*, 397 U.S. 112 (1970), that federal statutes of limitations should be applied strictly in order to further the congressional policy favoring repose.” *Hare*, 618 F.2d at 1086-87.

Here, similarly, even assuming a prior false or misleading statement that the EIR incorporated, the failure to correct the statement is not a crime absent any duty to make a correction, and was not an “act” in furtherance of the conspiracy that could extend the limitations

period. *See, e.g., United States v. Curran*, 20 F.3d 560, 571 (3d Cir. 1994) (“If a jury is misled into considering as unlawful the omission of an act that the defendant is under no duty to perform, then a finding of conspiracy based on such conduct cannot stand. It follows that the conspiracy count must therefore be vacated.”); *Ritchie Capital Mgmt., L.L.C. v. Gen. Elec. Cap. Corp.*, 121 F. Supp. 3d 321, 339 (S.D.N.Y. 2015), *aff’d*, 821 F.3d 349 (2d Cir. 2016) (“Courts have held that the ‘overt act’ typically must be an affirmative act; mere inaction is insufficient.”); *Kirschner as Tr. of Millennium Lender Claim Tr. v. JPMorgan Chase Bank, N.A.*, 2021 WL 4499084, at \*24 (S.D.N.Y. Sept. 30, 2021) (same).

## **II. Improperly Extending The Statute Of Limitations Is Both Unfairly Prejudicial And Contrary To Policy**

There is good reason for the practice of applying statutes of limitations strictly. *See Toussie, Hare, supra; see also United States v. Habig*, 390 U.S. 222, 227 (1968). Indeed, this case—with its gap of nearly a decade since the accomplishment of the object of the conspiracy—perfectly illustrates why statutes of limitations “reflect[] a policy judgment by the legislature that the lapse of time may render criminal acts ill-suited for prosecution.” *Smith v. United States*, 568 U.S. 106, 112 (2013).

As reflected in the government’s error regarding Mr. Vepuri’s alleged participation in a meeting from which he was demonstrably absent, “[l]imitations statutes . . . are intended to foreclose the potential for ***inaccuracy and unfairness that stale evidence and dull memories may occasion*** in an unduly delayed trial,” and “provide relief from extended pretrial anxieties and, by encouraging investigation of recent crimes, contribute to a rational allocation of prosecutorial resources.” *United States v. Levine*, 658 F.2d 113, 127 (3d Cir. 1981) (emphasis added); *see also United States v. Marion*, 404 U.S. 307, 322 (1971) (noting statutes of limitations “provide

predictability by specifying a limit beyond which there is an irrebuttable presumption that a defendant's right to a fair trial would be prejudiced").

This case perfectly reflects the hazards of continued government investment of still further resources in alleged conduct now more than a decade old, and that—even if accepted as true—resulted in harm to no one. To the extent there remains any doubt as to the viability of the government's conspiracy charge in light of Mr. Vepuri's statute of limitations argument, strict application of the statute of limitations warrants dismissal.

**CONCLUSION**

For the foregoing reasons, Mr. Vepuri's Motion to Dismiss the Superseding Indictment As Time Barred Under Federal Rule Of Criminal Procedure 12 should be granted.

Respectfully submitted,

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Dated: December 1, 2021

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**CERTIFICATE OF SERVICE**

I hereby certify that, on this date, I served a copy of *Defendant Murty Vepuri's Motion to Dismiss the Superseding Indictment and Memorandum in Support thereof* upon the following via ECF and e-mail:

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